

### **REMARKS**

In response to the Office Action of August 6, 2003, claims 1-33 have been cancelled without prejudice to pursuing such claims in a divisional application. Claims 34 and 35 have been amended to clarify the claimed invention in independent Claim 34, and to correct typographical errors by changing “from” to “for” in Claim 34 and by pluralizing “path” in Claim 35. Applicant hereby affirms that a provisional election was made with traverse on July 8, 2003, and elects to prosecute the invention of Group IV, claims 34-45. Claims 34-45 remain in the application. Applicant hereby requests reconsideration of the application, in view of these amendments and the remarks which follow.

#### **Brief Description of Applicant's Claimed Invention**

As set forth in currently amended claim 34, Applicant's claimed invention is directed to a biological suspension processing system comprising a blood treatment device for treating one or more components of a biological suspension; a human subject; a first fluid flow path communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device; a second fluid flow path communicating with the treatment device for withdrawing a constituent of the blood from the treatment device; a third fluid flow path communication with the treatment device for withdrawing another constituent of the blood from the treatment device; and at least one microelectromechanical sensor communicating with one of said fluid flow paths for sensing a selected characteristic of the fluid within the flow path.

More specifically and in contrast to the cited prior art, Applicant's claimed invention is clearly an *in vivo* biological suspension processing system whereby the first fluid flow path is in continuing, direct communication with the vascular system of the human subject. Also, the purpose of the microelectromechanical sensor is to sense a selected characteristic of the fluid within the flow path, such as red cell or white cell count, hematocrit, blood type, etc., rather than transport characteristics of the fluid stream, e.g. pressure or flow rate.

*Mian Does Neither Discloses Nor Suggests Continuing and Direct Communication with a Human Subject.*

Claims 34-36 and 38-45 stand rejected under 35 U.S.C. §102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1), hereinafter “Mian.” The office action states that Mian discloses the biological suspension processing system as claimed by the Applicant. More specifically, it states that “Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger; at this time, the fluid flow path of C1 is in communication with the vascular system of the patient.” Moreover, according to the Office Action, “a plurality of flow paths C2-C5 are provided for receiving the separated components (280) to (285), wherein the components can be withdrawn from the device (286). The device is a microanalytic system that includes electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218).”

Applicant’s claimed invention is readily distinguished from Mian and the attempted combination of various aspects of Mian as set forth by the office action. More specifically, Applicant’s claimed invention is clearly an *in vivo* biological suspension processing system whereby the first fluid flow path is in continuing and direct communication with the vascular system of the human subject, rather than the lancet puncture system as described in Mian. In contrast to the claimed invention, Mian’s Blood Composition Determination device has a first, second, and third fluid flow path routed in a circular arrangement about a disk. (¶284) Mian describes introducing fluid to the first fluid flow path of the disk through applying a blood droplet produced by a prick of a lancet (¶280), which is far different from the continuing communication with the vascular system of the patient set forth in the pending claim.

In an apparent attempt to overcome the above deficiency in the teaching of Mian, the office action cites disparate sections of paragraph 216 which states that a disk may have integral lancets attached thereto. However, this also does not meet or suggest the claimed subject matter. Mian clearly describes an *in vitro* system, whereby the communication, via a lancet between the first fluid flow path and the patient is necessarily momentary and temporary. The first fluid flow path must be separated from the patient in order to analyze the constituents therein. See Fig. 19 and its description thereof ¶¶0280-0287.

In contrast, Applicant discloses an *in vivo* biological suspension processing system whereby the first fluid flow path is in continuing, direct communication with the vascular system of the human subject. See Flow chart, Fig.1 and its description thereof, pgs. 20-25. As opposed to the momentary and temporary communication of a lancet, as described in Mian, Applicant's claimed invention allows for an extended communication with the vascular system, thereby allowing for an *in vivo* biological suspension processing system. It is important to note that this continuing, direct communication does not necessarily extend over the length of the entire treatment and analysis of the fluid. In turn, it is equally important to note that this continuing, direct communication is unlike and not suggested by the temporary prick from a lancet as taught in Mian. It is respectfully submitted that Mian does not teach or suggest a "first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device" as now claimed.

In view of the foregoing amendment and remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(e) rejection and allowance of these claims.

*The Prince-Bullister Combination does not Render Applicant's Claimed Invention Obvious*

Claims 34-35 and 37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Prince (U.S. Patent 5,178,603) in view of Bullister et al. (U.S. 6,171,253 B1). The office action states that "Prince teaches an apheresis system for the treating/returning blood to a patient via the system shown in figure 1 including a plasma separator (treatment device) and blood pump controlling blood flow to the device and including numerous pressure sensors." The office action correctly states that Prince does not disclose a MEM sensor. However, when combined with the MEM blood pressure sensor of Bullister, the Prince-Bullister combination renders Applicant's claimed invention obvious.

Applicant submits that Prince teaches a system for controlling blood flow through blood pressure sensors, but does not teach using MEM blood pressure sensors. In an effort to overcome this deficiency, the office action combines Prince with Bullister which teaches MEM blood pressure sensors. Nevertheless, this Prince-Bullister combination does not render

Applicant's claimed invention as obvious. In contrast to both Prince and Bullister, Applicant's claimed invention is directed to using a microelectromechanical sensor "for sensing a select characteristic of the fluid within the flow path." The language of this element of Applicant's independent claim 34 is intended to be directed to using a microelectromechanical sensor for sensing a selected characteristic of the fluid itself rather than the transport characteristics of the fluid stream such as flow rate or pressure as mentioned in Prince.

For example, in the specification, Applicant has described the use of MEM sensors in sensing and detecting red cell count, platelet count, lipid level, blood type, markers representative of pathogen (viral or bacterial presence), white cell count, red cell hematocrit, platelet density, platelet dose, pH, or gas partial pressure. *See* pg. 22, lns 9-11; pg. 23, lns. 9-11; pg. 24, lns. 9-10 of the specification. It is important to note that the foregoing list is not comprehensive, but is merely exemplary of the characteristics that may be sensed. Other such characteristics may be sensed so long as it is a characteristic of the fluid itself. Therefore, Applicant's claimed invention may be readily distinguished from the Prince-Bullister combination.

Accordingly, in view of the foregoing remarks, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) obviousness rejection and allowance of these claims.

### Conclusions


Claims 34-36 and 38-45 stand rejected under 35 U.S.C. §102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1). In response to this rejection, Applicant has submitted that the claimed invention is readily distinguishable from the teachings of Mian and has amended independent claim 34 in order to more clearly claim a "first fluid flow path, wherein said first fluid flow path is in continuing, direct communication with the vascular system of the human subject and the treatment device for introducing blood from the human subject into the treatment device."

Claims 34-35 and 37 further stand rejected under 35 U.S.C. §103(a) as being unpatentable over Prince (U.S. Patent 5,178,603) in view of Bullister et al. (U.S. 6,171,253 B1). Applicant has submitted that independent claim 34 is readily distinguishable from the cited references and, more specifically, is intended to be directed to using a microelectromechanical

sensor for sensing a selected characteristic of the fluid itself rather than the transport characteristics of the fluid stream such as flow rate or pressure as mentioned in Prince. In view of the foregoing, Applicant respectfully requests withdrawal of the §102(e) and §103(a) rejections and allowance of independent claim 34. The remaining claims 35-45 are dependent on independent claim 34 and, therefore, include all of its claim limitations therein. Accordingly, Applicant also requests withdrawal of the §102(e) and §103(a) rejections with respect to these claims.

In view of the foregoing, reconsideration and allowance of all pending claims are respectfully requested.

Respectfully submitted,  
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